

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

In re application of:

David Hung et al.

Atty. Docket: 005284.00196

Examiner: Unknown

Group Art Unit: 3763

Serial No.: To Be Assigned
(Continuation of Serial No.: 10/072,911)

Filed: June 27, 2003

For: Apparatus, Methods and Kits For Simultaneous Delivery Of A
Substance To Multiple Breast Milk Ducts

INFORMATION DISCLOSURE STATEMENT UNDER 37 C.F.R. § 1.97(b)

Commissioner for Patents
P.O. Box 1450
Alexandria, VA 22313-1450

Sir:

Pursuant to their duty of good faith and candor as set forth in 37 C.F.R. § 1.56(a)
Applicants submit herewith the references cited on the attached PTO-1449 forms.

Copies of these references are not submitted herewith, but can be found in parent
application file U.S. Serial No. 10/072,911.

Applicants respectfully request that the Examiner consider these references in connection
with the search of the prior art required by 37 C.F.R. § 1.104.

It is believed that no fee is required to ensure consideration of the cited references by the
Examiner. However, if a fee is deemed necessary, the Commissioner is authorized to charge our
Deposit Account No. 19-0733.

Respectfully submitted,

Brian E. Hanlon

Brian E. Hanlon

Reg. No. 40,449

Date: 6/27/03
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1001 G Street, N.W.
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FORM PTO-1449 (Modified)			Attorney Docket No.: 005284.00196		Application No.: TBA	
LIST OF PATENTS AND PUBLICATIONS FOR APPLICANT'S INFORMATION DISCLOSURE STATEMENT (Use several sheets if necessary)			Applicant: DAVID HUNG et al.			
			Filing Date: June 27, 2003		Group: 3763	
Reference Designation			U.S. PATENT DOCUMENTS			Page 1 of 5
Examiner Initial	Document No.	Date	Name	Class	Sub-class	Filing Date (If Appropriate)
AA	3,608,540	09/28/00	Sartorius			
AB	3,786,801	1/22/74	Sartorius			
AC	3,821,956	7/2/74	Gordhammer, et al.			
AD	4,406,653	9/27/83	Nunez			
AE	4,543,087	9/24/85	Sommercorn, et al.			
AF	4,613,329	9/23/86	Bodicky			
AG	4,739,768	4/26/88	Engelson			
AH	4,790,830	12/13/88	Hamacher			
AI	4,795,424	1/3/89	Barner, et al.			
AJ	4,878,903	11/07/89	Mueller			
AK	4,957,484	9/18/90	Murtfeldt			
AL	5,176,647	1/5/93	Knoepfler			
AM	5,183,470	2/2/93	Wetterman			
AN	5,279,551	1/18/94	James			
AO	5,300,022	04/05/94	Klapper et al.			
AP	5,333,609	8/2/94	Bedingham, et al.			
AQ	5,350,358	9/27/94	Martin			
AR	5,364,344	11/15/94	Beattie, et al.			
AS	5,368,574	11/29/94	Antonacci, et al.			
AT	5,593,393	1/14/97	Trudell, et al.			
AU	5,599,324	2/4/97	McAlister			
AV	5,637,102	6/10/97	Tolkoff, et al.			
AW	5,649,909	7/22/97	Cornelius			
AX	5,683,640	11/4/97	Miller, et al.			
AY	5,702,365	12/30/97	King			
AZ	5,704,925	1/6/98	Otten et al.			
BA	5,795,326	8/18/98	Siman			
BB	5,797,869	8/25/98	Martin et al.			
BC	5,807,329	9/15/98	Gelman			
BD	5,810,789	09/22/98	Powers et al.			
BE	5,810,867	9/22/98	Zarbatany			
BF	5,827,237	10/27/98	Macoviak et al.			
FOREIGN PATENT DOCUMENTS						
	Document No.	Date	Country	Class	Sub-class	Translation (Yes/No)
BG	EP 448,395	09/25/91	Europe			

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Substitute for form 1449A/PTO

**INFORMATION DISCLOSURE
STATEMENT BY APPLICANT**

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Filing Date	June 27, 2003
First Named Inventor	David Hung
Group Art Unit	3763
Examiner Name	Unknown
Attorney Docket Number	005284.00196

U.S. PATENT DOCUMENTS

Examiner Initials *	Cite No. ¹	Document Number	Publication Date MM-DD-YYYY	Name of Patentee or Applicant of Cited Document	Pages, Columns, Lines, Where Relevant Passages or Relevant Figures Appear
		Number - Kind Code ² (if known)			
		US-4,925,452	05/15/1990	Melinyshyn et al.	
		US- 5,322,519	06/21/1994	Ash	
		US- 5,891,111	04/06/1999	Ismael	
		US- 5,904,715	05/18/1999	Jeter et al.	
		US- 6,221,622	04/24/2001	Love	
		US- 5,683,420	11/04/1997	Jeter et al.	
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FOREIGN PATENT DOCUMENTS

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		Country Code ³ - Number ⁴ - Kind Code ⁵ (if known)				

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¹ Applicant's unique citation designation number (optional). ² See Kinds Codes of USPTO Patent Documents at www.uspto.gov or MPEP 901.04.³ Enter Office that issued the document, by the two-letter code (WIPO Standard ST.3). ⁴ For Japanese patent documents, the indication of the year of the reign of the Emperor must precede the serial number of the patent document. ⁵ Kind of document by the appropriate symbols as indicated on the document under WIPO Standard ST. 16 if possible. ⁶ Applicant is to place a check mark here if English language Translation is attached.

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OTHER PRIOR ART -- NON PATENT LITERATURE DOCUMENTS

Examiner Initials *	Cite No. ¹	Include name of the author (in CAPITAL LETTERS), title of the article (when appropriate), title of the item (book, magazine, journal, serial, symposium, catalog, etc.), date, page(s), volume-issue number(s), publisher, city and/or country where published.	T ²
		Barsky, et al. "Pathologic analysis of breast duct endoscoped mastectomies" Proc. Annual Meeting Am. Assoc. Cancer Res. 34, abstracts #67	
		"Breast Fluid Cells Help In Early Cancer Detection" JAMA, Vol. 224, No. 6, May 7, 1973	
		Leborgne, "The Breast In Roentgen Diagnosis", Uruguay 1953	
		Makita, et al. "Duct Endoscopy and Endoscopic Biopsy in the Evaluation of Nipple Discharge", Breast Cancer Research and Treatment, 18: 179-188, 1991	
		Okazaki, et al., "Relationship Between Cytologic Results and the Extend of Intraductal Spread in Nonpalpable Breast Cancers With Nipple Discharge", Tumor Res. 31, 89-97, 1996	

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		Wrensch et al, Breast Cancer Res Treat, Factors associated with obtaining nipple aspirate fluid: Analysis of 1428 women and literature review, Vol. 15, pp 39-21, 1990	
		Wrensch et al, Breast Fluid Cholesterol and Cholesterol B-Epoide Concentrations in Women with Benign Breast Disease, Cancer Res., Vol. 49, pp 2168-2174, 1989	
		Mechanical Engineering, Vol. 118 (10), pp 65-68, 1996	
		King et al, Analytic Studies of Foam Cells From Breast Cancer Precursors, Cytometry, Vol. 5, pp 124-130, 1984	
		King et al, Cellular Composition of the Nipple Aspirate Specimen of Breast Fluid, A.J.C.P., Vol. 64, pp 739-748, 1975	
		King et al, Cellular Composition of the Nipple Aspirate Specimen of Breast Fluid, A.J.C.P., Vol. 64, pp 728-738, 1975	
		Masood et al, The Missing Link: A "Pap Smear" For Early Breast Cancer Detection and Prevention, The Breast Journal, Vol. 5, pp 1-2, 1999	
		Sartorius et al, Cytologic Evaluation of Breast Fluid in the Detection of Breast Disease, Journal of National Cancer, Vol. 59, pp 1073-1080, 1977	
		Sauter et al, Nipple aspirate fluid: a promising non-invasive method to identify cellular markers of breast cancer risk, British J. Cancer, Vol. 76(4), pp 494-501, 1997	
		Wrensch et al, Breast Cancer Incidence in Women with Abnormal Cytology in Nipple Aspirates of Breast Fluid, Amer J. Epid., Vol. 135, pp 130-141, 1992	
		Frykberg and Masood Copeland EM 3d Bland KI., (Ductal carcinoma in situ of the breast) Surgery, Gynecology & Obstetrics, Vol. 177 (4), pp 425-40, 1993	

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		Papanicolaou et al, Exfoliative Cytology Of The Human Mammary Gland And Its Value In The Diagnosis Of Cancer And Other Diseases Of The Breast, Cancer, Vol. 11, pp 377-409, 1958	
		Goodson WH & King EB, Chapter 4: Discharges and Secretions of the Nipple, The Breast: Comprehensive Management of Benign and Malignant Diseases, 2 nd Ed., Bland & Kirby Eds. W.B. Saunders Co, Philadelphia, PA, Vol. 2, pp 51-74, 1998	
		King et al, Nipple Aspirate Cytology for the Study of Breast Cancer Precursors, Journal of the National Cancer Institute, Vol 71(6), pp 1115-21, 1983	
		Wrensch et al, Breast Cancer Incidence in Women with Abnormal Cytology in Nipple Aspirates of Breast Fluid, Am. J. Epidemiology, Vol. 135 (2), pp 130-141, 1992	
		Sauter et al, Nipple aspirate fluid: a promising non-invasive method to identify cellular markers of breast cancer risk, British Journal of Cancer, Vol. 76 (4), pp 494-501, 1997	
		Sartorius et al, Cytologic Evaluation of Breast Fluid in the Detection of Breast Disease, Journal of the National Cancer Institute, Vol. 59 (4), pp 1073-80, 1977	
		Love and Barsky, Breast-duct endoscopy to study stages of cancerous breast disease, Lancet, Vol. 348(9033), pp 997-9, 1996	
		Makita et al, Duct endoscopy and endoscopic biopsy in the evaluation of nipple discharge, Breast Cancer Res Treat Vol. 18, pp 179-188, 1991	
		Okazaki et al, Fiberoptic Ductoscopy of the Breast: A New Diagnostic Procedure for Nipple Discharge, Jpn J. Clin. Oncol. Vol. 21, pp 188-193, 1991	
		Petrakis, Studies on the Epidemiology and Natural History of Benign Breast Disease and Breast Cancer Using Nipple Aspirate Fluid, Cancer Epidemiology, Biomarker Prev., Vol. 2, pp 3-10, 1993	
		Petrakis, Physiologic, biochemical, and cytologic aspects of nipple aspirate fluid, Breast Cancer Res. Treat, Vol. 8, pp 7-19, 1986	

Examiner Signature		Date Considered	
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